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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,452	09/19/2003	Lisa Tam	000717.00012	7275

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BANNER & WITCOFF
1001 G STREET N W
SUITE 1100
WASHINGTON, DC 20001

EXAMINER

JACKSON, BRANDON LEE

ART UNIT

PAPER NUMBER

3772

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/665,452

Applicant(s)

TAM ET AL.

Examiner

Brandon Jackson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-32 is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 12/19/03 and 3/30/04.
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1- 24, and 27-29 rejected under 35 U.S.C. 103(a) as being unpatentable over Lash (U.S. Patent 4,867,176) in view of Harmon (U.S. Patent 5,137,032). Lash discloses a female condom (21) comprising a pouch (22) of resilient membranous material having an open end (24), a closed end (23), an outer surface (28), an inner surface (fig. 4), and a longitudinal axis (fig. 4). Further, the lash condom comprises an inserter (37) coupled to said pouch (22) for retaining a distal portion (23) and facilitating insertion of said female condom (21) into a vagina. The inserter (37) is attached to said pouch (22). The pouch (22) is slidably inserted in the inserter (37). The inserter (37) expands to cling to the walls of the vagina and hold the female condom (21) in position

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for usage. The inserter (37) is elastomeric as it compresses to enter the vagina, and then expands after insertion hold position with in the vagina (col.4, lines 23-28). Also, Lash discloses a packaged (fig. 16) female condom (21), wherein the condom and applicator are received within a cap-like receptacle or inserter. Lash fails to disclose hydrophilic cling elements attached to the outer surface of the female condom and adapted to anchor said pouch in or slightly beyond the vagina's introitus. Hydrophilic cling elements defined generally by a triangular or circular shape. As well as, the inserter being formed of the same material as the cling element and being dissolvable. However, Harmon teaches a plurality of hydrophilic (col. 4, line 30) friction-imparting agents or cling elements (20) disposed in a belt-like pattern. The friction-imparting agent (20) is defined generally by an elliptical shape and is water-soluble (col. 4, line 39). The segment that holds the hydrophilic friction-imparting agent (20) to the condom can be made materials including hydrophilic polyurethane (col. 4, lines 45-50). The friction-imparting agent (20) clings to the vaginal walls in order to stabilize the condom within the vagina (col. 2-3, lines 62-66, 1-3). Harmon teaches the use of water-soluble and dissolvable material, polyvinyl alcohol (col. 4, lines 35-40) for portions connected to the condom. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the female condom of Lash with the friction-imparting agents as taught by Harmon, and substitute the material of Lash for polyvinyl alcohol foam as taught by Harmon; because the friction-imparting agents of Harmon would give the female condom of Lash more stability and help to ensure minimal movement of the condom during intercourse. Moreover, the polyvinyl alcohol foam is

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meant to be used with contraceptive devices and would work equally as well with the inserter of Lash.

With respect to claim 8, Applicant has not asserted that the total surface area of the hydrophilic cling element of .75 square inches provides a particular advantage, solves a stated problem, or severs a purpose different from that of any hydrophilic frictional element connected to a condom, thus the .75 square inches lack criticality in its design. Therefore, one of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with friction-imparting agent of Harmon because they both perform the same function of frictionally clinging to the walls of the vagina for reason of immobilizing a condom.

Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lash/Harmon as applied to claim 13 above, and further in view of Feng (U.S. Patent 6,170,484). Lash/Harmon disclose: see above rejection of claim 23. Also, Lash/Harmon disclose a plurality of longitudinal pleats (61) formed in the distal portion of the pouch (fig. 12) However, Lash/Harmon fail to disclose a plurality of pleats formed in the circumferential direction of the distal portion of the pouch. However, Feng teaches a plurality of longitudinal and horizontal pleats (fig. 6) on a female condom (101). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the condom of Lash/Harmon with the pleats as taught by Feng, because they allow for the easy application of the female condom.

Allowable Subject Matter

Claims 30-32 are allowed because the prior art made of record does not teach or fairly suggest a method of packing a female condom wherein said female condom's lateral and longitudinal pleats are collapsed along the longitudinal axis into an inserter about the distal portion. The pouch of the female condoms is placed over a mandrel and air disposed between the pouch and mandrel is withdrawn and the pouch collapses about the mandrel. Then, where folding the female condom comprises rotating each of the longitudinal pleats clockwise or counter-clockwise and wherein the step of forming lateral pleats comprises sliding said distal portion about the mandrel disposed within an inner cavity, and the step of placing an inserter about said collapsed distal portion comprising turning at least one portion of the cap inside-out to retain said distal portion.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shields et al. (U.S. Patent 5,209,242) and Reddy (U.S. Patent 5,325,871).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon Jackson whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon Jackson
Examiner
Art Unit 3772

BJ

AlBianco
12/11/06